510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APPLICANT INFORMATION

A.	Company Name:	KFx Medical, Inc
B.	Company Address:	5845 Avenida Encinas Suite 128 Carlsbad, CA 92008
C.	Company Phone:	(760) 444-8844
D.	Company Facsimile:	(760) 602-9252
E.	Contact Person:	Gayle Hirota QA/RA

DEVICE IDENTIFICATION

A.	Trade Name:	KFx 5.5mm Suture Lock Bone Screw Anchor
B.	Common Name:	Bone Anchor
C.	Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue
D.	Product Code:	MBI
E.	Device Panel:	Orthopedic
F.	Device Class:	Class II

IDENTIFICATION OF MODIFIED DEVICE

The KFx 5.5mm Suture Lock Bone Screw Anchor is similar in basic design and intended use to the KFx Medical Suture Lock Bone Anchor, cleared under 510(k) K072063.

DEVICE DESCRIPTION

The KFx Tissue Fixation System is intended for the fixation of soft tissue to bone using Teleflex ForceFiber® #2 braided suture. The KFx 5.5mm Suture Lock Bone Screw Anchor component of the Tissue Fixation System is used to capture the Nail Bone Anchor sutures, eliminating the need to tie suture knots.

The KFx Nail Bone Anchor and the KFx Suture Lock Bone Screw Anchors are provided "STERILE"; sterilization is by Ethylene Oxide (EO) gas.

INTENDED USE

The intended use of the KFx 5.5mm Suture Lock Bone Screw Anchor is for the fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow.

Specifically:

Shoulder: Bankart lesion repairs, SLAP lesion repairs, acromio-clavicular separation repairs, rotator cuff repairs, capsular shift or capsulolabral reconstructions, biceps tenodesis, deltoid repairs.

Foot and Ankle: Hallux valgus repairs, medial or lateral instability repairs/reconstructions, Achilles repairs/reconstructions, mid-foot reconstructions, metatarsal ligament repair.

Knee: Medial collateral ligament repairs, lateral collateral ligament repairs, posterior oblique ligament repairs, Iliotibial band tenodesis, patellar tendon repairs.

Hand, Wrist and Elbow: Scapholunate ligament reconstructions, ulnar or radial collateral ligament reconstructions, tennis elbow repair, biceps tendon reattachment.

EQUIVALENT DEVICE

The KFx 5.5mm Suture Lock Bone Screw Anchor is similar in basic design, technology, construction and mechanical performance to the Suture Lock Bone Anchor included in the KFx Tissue Fixation System previously cleared under 510(k) K072063. Intended use is identical. Device modifications include use of an additional biocompatible material, reduction in size, and packaging.

BIOCOMPATIBILITY AND PERFORMANCE DATA

The materials used in the KFx 5.5mm Suture Lock Bone Screw Anchor are biocompatible. The same materials are used in a myriad of legally marketed orthopedic devices.

Bench test results indicate that the device is safe and satisfies functional performance requirements when used as indicated and do not raise new issues of safety or effectiveness.

CONCLUSIONS DRAWN FROM STUDIES

The test results demonstrate that the modified KFx 5.5mm Suture Lock Bone Screw Anchor is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 29 2008

KFx Medical
% Ms. Gayle Hirota
QA/RA Director
5845 Avenida Encinas
Suite 128
Carlsbad, CA 92008

Re: K080229
Trade/Device Name: KFx 5.5mm Suture Lock Bone Screw Anchor, a component of the KFx Tissue Fixation System and Accessories
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: January 29, 2008
Received: January 30, 2008

Dear Ms. Hirota:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1.7 Indications for Use

510(k) Number (if known): K080229

Device Name: KFx 5.5mm Suture Lock Bone Screw Anchor (component of the KFx Tissue Fixation System and Accessories)

Indications For Use: The KFx Tissue Fixation System (comprised of the KFx Suture Lock Bone Screw Anchor and KFx Suture Lock Nail Bone Anchor) and Accessories are intended for the fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow.

Specifically:

Shoulder: Bankart lesion repairs, SLAP lesion repairs, acromio-clavicular separation repairs, rotator cuff repairs, capsular shift or capsulolabral reconstructions, biceps tenodesis, deltoid repairs

Foot and Ankle: Hallux valgus repairs, medial or lateral instability repairs/reconstructions, Achilles repairs/reconstructions, mid-foot reconstructions, metatarsal ligament repair.

Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, Iliotibial band tenodesis, patellar tendon repair.

Hand/Wrist/Elbow: Scapholunate ligament reconstructions, ulnar or radial collateral ligament reconstructions, tennis elbow repair, biceps tendon reattachment.

Prescription Use X AND/OR Over-The-Counter Use No
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Mulkerin

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices Page 1 of 1

510(k) Number K080229

CONFIDENTIAL